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510(k) Summary, COVAMESH™

OCT 25 2013

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Date Summary was prepared: October 24, 2013

Trade/Proprietary Name: COVAMESH™
Common/Usual Name: Surgical Mesh
Classification : Mesh, Surgical
Product Code: FTL
Regulation Number: 21 CFR 878.3300
Device Classification: Class II

Predicate Devices PARIETEX® COMPOSITE Mesh (K040998)
Cova™ORTHO NERVE (K103081)

Device Description

COVAMESH™ is a surgical mesh used during open procedures (laparotomy) or during laparoscopic procedures. COVAMESH™ is made from polyethylene terephtalate (polyester) and a cross-linked resorbable collagen film of porcine origin. The hydrophilic collagen film physically separates the coated side of the mesh from adjacent tissue, viscera, and organs. A marking with a non-resorbable ink is at the centre of the mesh to help positioning the device. The surgical mesh is obtained by standardized, controlled manufacturing processes. COVAMESH™ is further sterilized in double-blisters by gamma-irradiation.

COVAMESH™ is designed to be non inflammatory and biocompatible to allow reinforcement of soft tissues. When wetted, the surgical mesh is rollable to be easily introduced in a trocar. COVAMESH™ is suturable in place. It is provided in round sheets of 12 cm diameter and 16cm diameter and in rectangular sheets of 15x10 cm, 20x15 cm, 25x20 cm, 30x20 cm, 36x30 cm.

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Intended Use

COVAMESH™ is intended for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-resorbable three dimensional polyester mesh provides long-term reinforcement of soft tissues.

Technological Characteristics and Substantial Equivalence

The intended use, product design, physical structure and target population of COVAMESH™ is substantially equivalent to the FDA cleared and legally marketed predicate device PARIETEX® COMPOSITE Mesh (K040998). COVAMESH™ is constructed of a three-dimensional polyester mesh, knitted into a structure similar to PARIETEX® COMPOSITE Mesh (K040998). The collagen component is derived from a porcine source already cleared by FDA for predicate Cova™ORTHO-NERVE (K103081). In addition, COVAMESH™ and predicate devices are available in various sizes and shapes to accommodate different surgical procedures and/or surgeon's choice. Similarities are presented in the following Table.

Any differences in technological characteristics between the COVAMESH™ and the predicate devices do not raise any new issues of safety or efficacy. The performance and safety of the material used was evaluated. The collective results have demonstrated that the COVAMESH™ is substantially equivalent to the respective predicate devices with regard to safety and efficacy.

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Table 1 - COVAMESH™ and its predicates summarized comparison chart.

Name	COVAMESH™	PARIETEX® COMPOSITE Mesh (K040998)	Cova™ ORTHO-NERVE (K103081)
Composition **Origin**	Type I collagen, polyester Porcine collagen	Type I collagen, polyester Porcine collagen	Type I collagen Porcine collagen
Intended use	Indicated for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-resorbable three dimensional polyester mesh provides long-term reinforcement of soft tissues.	Indicated for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-resorbable three dimensional polyester mesh provides long-term reinforcement of soft tissues. On the opposite side, the resorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.	Indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity.
Characteristics	Hydrophilic film on a 3D polyester mesh Easy to manipulate Smooth (hydrophilic film) Flexible Wettable Rollable	Hydrophilic film on a 3D polyester mesh Easy to manipulate Smooth (hydrophilic film) Flexible Wettable Rollable	Hydrophilic film Easy to manipulate Smooth (hydrophilic film) Flexible Wettable Rollable
Biocompatibility **Non-pyrogenic** **Resorbable** **Suturable**	Established Yes Yes (collagen film) Yes	Established Yes Yes (collagen film) Yes	Established Yes Yes (collagen film) Yes
Reusable **Shelf-life**	Single use 6 months	Single use 36 months	Single use 24 months
Packaging **Sterilization**	Double-peel packages Gamma irradiation	Double-peel packages Gamma irradiation	Double-peel packages Gamma irradiation

Safety Evaluation

Biocompatibility testing was performed according to the FDA Blue Book Memorandum G95-1 and ISO 10993-1. COVAMESH™ passed all of the following tests:

- Cytotoxicity,
- Sensitization,
- Irritation,
- Systemic Toxicity (Acute),
- Genotoxicity– Ames Mutagenesis,
- Genotoxicity – Bone Marrow Micronucleus,
- Genotoxicity – Mouse Lymphoma Mutagenesis,
- Implantation,
- Pyrogenicity,
- Sub-Chronic/Chronic Toxicity.

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The COVAMESH™ manufacturing process complies with the United States Food and Drug Administration and European Standards for animal tissue sourcing and viral inactivation.

Summary of Effectiveness Data

Bench testing
Bench testing was conducted in accordance with FDA guidance – Preparation of a Premarket Notification Application Surgical Mesh to evaluate the performance characteristics of COVAMESH™. The thickness, pore size, density, tensile strength, suture pullout strength and tear resistance were all evaluated. The test results showed that COVAMESH™ has similar performance characteristics as previously cleared surgical mesh. Any differences in technological characteristics between the COVAMESH™ and the predicate devices do not raise any new issues of safety or efficacy.

Animal Data
In vivo performances testing on two representative animal models were conducted in comparison with the predicate PARIETEX® COMPOSITE Mesh (K040998). The results demonstrate that COVAMESH™ elicits a similar tissue response and has similar tissue integration as compared to the PARIETEX® COMPOSITE Mesh predicate device.

Conclusion

COVAMESH™ is substantially equivalent to its predicate devices: PARIETEX® COMPOSITE Mesh (K040998) and Cova™ ORTHO-NERVE (K103081).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 25, 2013

Biom'Up S.A.
Ms. Valeria Centis
R&D Project Manager and Regulatory Affairs
8, Allee Joliot-Curie
69800 Saint Priest
FRANCE

Re: K130428
Trade/Device Name: COVAMESH™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 18, 2013
Received: September 23, 2013

Dear Ms. Centis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130428

Device Name
COVAMESH™

Indications for Use *(Describe)*

Intended for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-resorbable three dimensional polyester mesh provides long-term reinforcement of soft tissues.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S